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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/697,356 | 10/29/2003 | Kenneth F. Buechler | 071949-2705 | 7520 |

30542 7590 05/03/2006

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| EXAMINER | |
|---|---|
| CHEU, CHANGHWA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/697,356 | BUECHLER, KENNETH F. | |
| | Examiner | Art Unit | |
| | Jacob Cheu | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendment and Affidavit 132 under Rule 131 filed on 2/15/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claim 11-16 are cancelled.
2. Claim 1-10 and 17 are under examination.

***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1, 8, 9, 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 11-19 of U.S. Patent No. 5947124. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim drawn to a method for determining the ratio of oxidized cardiac troponin I to reduced cardiac troponin I in a myocardial infraction patient's sample by using two antibodies where the first antibody can recognize both oxidized and reduced form of troponin I, and the

second antibody can bind to either one of the oxidized and reduced first-antibody-troponin I complex, but do not form a complex with other said oxidized or reduced cardiac troponin I in the sample. The cited US 5947124 patent directs to a method of measuring a ratio of oxidized to reduced troponin I in a blood sample of myocardial infraction patients (claim 1) by using distinct components specific for troponin I (claim 12) where one of the distinct components is specific for both at least one oxidized form of troponin I and at least one of reduced form of troponin I (claim 15 and 19), and a second antibody is specific for either at least one oxidized form of troponin I, or at least one reduced form of troponin I (claim 13-14, 17-18). The performance is conducted for establishing a standard curve for analysis (claim 11).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1-10 and 17 a re rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, step (a)(ii), is vague and confusing, particular the phrase "whereby said first and second antibodies form a complex comprising one of said oxidized or reduced cardiac troponin I present in said sample, and do not form a complex comprising the other of said oxidized or reduced cardiac troponin I present in said sample". It is not clear whether the same second antibody form complex with the first

antibody-troponin I oxidized form will also form complex with the first antibody-troponin I reduced form. The recited language is not clear and applicant needs to clarify.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claim 1-10 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Buechler et al. (US 5947124).

It is noted that the instant invention does not contain information for assignment. Accordingly, it is treated as no-common assignee for art rejection purpose (See MPEP chapter 800, Chart II-B).

Buechler et al. teach a method of determining the ratio of oxidized cardiac troponin I to reduced cardiac tropinin I in a myocardial patient's blood sample (See claim 1). The method used by Buechler et al. comprises using a sandwich ELISA assay containing first antibody specific for both oxidized and reduced form of troponin I to form complex proportional to their ratio in the blood sample, and using a second antibody recognizing the first either oxidized or reduced form of tropnin I and measuring the signal corresponding to the amount of the first antibody-tropnin (reduced/oxidized)-second antibody (See claim 11-19; Col. 4, line 1-20).

With respect to claim 2, Buechler et al. teach labeling antibodies and immobilizing the microtiter for detection (Col. 6, line 40-60).

With respect to claim 3, Buechler et al. teach using enzyme, latex or silica particle attaching labeling materials for signal generation (Col. 7, line 58-66).

With respect to claim 4-6, Buechler et al. teach that the signal element can be of fluorescence detected by fluorometric apparatus or pH meter (Col. 7, line 64 to Col. 8, line 5).

With respect to claim 8-9, Buechler et al. teach using standard curve calculating the ratio of oxidized and reduced form of troponin I (claim 11).

With respect to claim 17, Buechler et al. teach using the ratio for diagnosis of myocardial infarction abnormality in patients (claim 1).

## *Response to Applicant's Arguments*

7. Applicant's arguments with respect to claims 1-5, 7, 10-13 and 17 have been considered but are moot in view of the new ground(s) of rejection.

8. The rejections of claim 1-5, 7, 10-13 and 17 under 35 USC 102 (b) as anticipated by Buechler et al. (WO 96/33415) is withdrawn.

## Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

April 24, 2006

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
04/20/06